510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) **Submitter's name, address, telephone number, contact person:**

Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116
Gary J. Allsebrook
Regulatory Affairs Consultant
Telephone: (510) 276-2648
Fax: (510) 276-3559
Email regman1@home.com
Prepared June 19, 2000

2) **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:
Diagnostic Ultrasound System and Accessories

Proprietary Name:
SA - 9900 Diagnostic Ultrasound System and Transducers.

Classification Names:

	FR Number	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3) Identification of the predicate or legally marketed device:

Medison America, Inc believes that SA-9900 Ultrasound system is substantially equivalent to the currently marketed Medison/Kretztechnik Combison 530D (K940942 & K992155), SonoAce SA-8800 (K974269) and SonoAce 6000C/Ultramark 400C (K990970 & K992470) .

4) Device Description:

SonoAce SA-9900:

The SonoAce SA-9900 scanner is a multiple-mode, multiple-application ultrasound imaging system. The cart-mounted console contains an ultrasound generator/receiver offering a full complement of conventional operating modes, software-based parameter controls, and recording. The selection of eight transducers to be offered with the system permits a wide range of clinical applications. The various transducers adapt the system for the specific imaging tasks.

Eight different models of transducers are available. In addition to the initial operational settings for each transducer preprogrammed in the system, user-customized parameter settings for each transducer may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit focusing, filtering, image enhancement processing, dynamic window curve selection. Controls are also provided to select display format (single and various combinations), to activate zoom features, and to utilize the cine loop function. Patient contact materials have been tested for biocompatibility in accordance to their intended use and are used for each individual transducer.

The SonoAce SA-9900 uses digital beamforming technology. The SonoAce SA-9900 supports a variety of Linear and Convex probes for wide variety of applications. It is an ultrasound scanner, which provides high resolution, high

penetration performance, and various measurement functions. Probes are supported in frequencies from 1.0 MHz to 20.0 MHz. The SonoAce SA-9900 provides high quality images and various measuring functions. Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of the SonoAce SA-9900 are B-Mode, M-Mode, Tissue Harmonic Imaging (THI), Color-flow Doppler, Continuous (CW) Doppler, Pulsed (PW) Doppler and Power Doppler. Management of patient history is possible by image-filing function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing. The same clinical uses were cleared for the predicate device(s), Medison/Kretztechnik Combison 530D (K940942 & K992155), SonoAce SA-8800 (K974269) and SonoAce 6000C/Ultramark 400C (K990970 & K992470) .

5) Intended Use:

- Fetal - OB/GYN
- Abdominal
- Small Organs (breast, thyroid, testicle)
- Pediatric
- Neonatal Cephalic
- Trans-Vaginal
- Trans-Rectal
- Peripheral Vascular
- Cardiac

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.

- Pediatric scans of organs, superficial, and bony structures.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Neonatal head studies.
- Podiatry scans of superficial structures including muscles, tendons and bones.
- General cardiac studies in adults.
- Prostate, bladder and rectum visualization.

6) Technological Characteristics:

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

I_{SPTAd}	720 mW/cm2	(maximum)
TIS/TIB/TIC	0.0 – 5.0	(Range)
MI	1.9	(Maximum)

The limits are the same as predicate Track 3 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2000

Medison America, Inc.
c/o Carole Stamp
TUV Product Service
1775 Old Highway 8, NW, Suite 104
New Brighton, MN 55112-1891

Re: K002185
Sonoace SA – 9900 Diagnostic Ultrasound System
Regulatory Class: II
21CFR 892.1550/Procode: 90 IYN
21CFR 892.1560/Procode: 90 IYO
21CFR 892.1570/Procode: 90 ITX
Dated: July 18, 2000
Received: July 19, 2000

Dear Ms. Stamp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sonoace SA – 9900 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

EC4-9ES, Curved Linear Array 6.5 MHz/10R/140D
L5-121R, Linear Array 7.5 MHz/40mm/192 elements
C2-51R, Curved Linear Array 3.5 MHz/40R/85D
P2-5AC, Phased Array 3.5 MHz
P3-7AC, Phased Array 4.5 MHz
2.0CW, Static CW 2.0 MHz
S-VAW3-5, Volume Curved Array 3.5 MHz
S-VAW4-7, Volume Curved Array 4.5 MHz
S-VDW5-8, Volume Curved Array 6.5 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for David A. Seguin

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Section 4.3
INDICATION FOR USE
Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*		N	N	N		N	N	Note 1	Note 2, 5, 6
Abdominal		N	N	N		N	N	Note 1	Note 2, 5, 6
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		N	N	N	N	N	N	Note 1	Note 2, 5, 6
Small Organ *(See Note 4)*		N	N	N		N	N	Note 1	Note 2, 5
Neonatal Cephalic		N	N	N	N	N	N	Note 1	Note 5, 6
Adult Cephalic		N	N	N	N	N	N	Note 1	Note 5, 6
Cardiac		N	N	N	N	N	N	Note 1	Note 5, 6
Transesophageal									
Trans-Rectal		N	N	N		N	N	Note 1	Note 2, 5
Trans-Vaginal		N	N	N		N	N	Note 1	Note 2, 5
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular		N	N	N		N	N	Note 1	Note 5
Laparoscopic									
Muscular-Skeletal Conventional		N	N	N		N	N	Note 1	Note 2, 5
Muscular-Skeletal Superficial		N	N	N		N	N	Note 1	Note 2, 5
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E Other Indications or Modes

Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging
Note 6: Harmonic Imaging
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Prescription Use (Per 21 CFR 801.109)

David A. Legnon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: EC4-9ES, Curved Linear Array 6.5MHz/10R/140D
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*									
Abdominal									
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric									
Small Organ *(See Note 4)*									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Trans-Rectal		N	N	N		N	N	Note 1	Note 2, 5
Trans-Vaginal		N	N	N		N	N	Note 1	Note 2, 5
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E
Other Indications or Modes
Note 1: PWD/Color Doppler, PWD/Power Doppler (N)
Note 2: Includes imaging for guidance of biopsy (N)
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (N)
Note 6: Harmonic Imaging
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David A. Legome
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: L5-12IR, Linear Array 7.5MHz/40mm/192elements
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*									
Abdominal									
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		N	N	N		N	N	Note 1	Note 2, 5
Small Organ *(See Note 5)*		N	N	N		N	N	Note 1	Note 2, 5
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Peripheral -Vascular		N	N	N		N	N	Note 1	Note 5
Laparoscopic									
Muscular-Skeletal Conventional		N	N	N		N	N	Note 1	Note 2, 5
Muscular-Skeletal Superficial		N	N	N		N	N	Note 1	Note 2, 5
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E
Other Indications or Modes
Note 1: PWD/Color Doppler, PWD/Power Doppler (N)
Note 2: Includes imaging for guidance of biopsy (N)
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (N)
Note 6: Tissue Harmonic Imaging
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David A. Legrow
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: C2-5IR, Curved Linear Array 3.5MHz/40R/85D
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*		N	N	N		N	N	Note 1	Note 2, 5, 6
Abdominal		N	N	N		N	N	Note 1	Note 2, 5, 6
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		N	N	N		N	N	Note 1	Note 2, 5, 6
Small Organ *(See Note 4)*									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E Other Indications or Modes
Note 1: PWD/Color Doppler, PWD/Power Doppler (N)
Note 2: Includes imaging for guidance of biopsy (N)
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (N)
Note 6: Tissue Harmonic Imaging (N)
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: P2-5AC, Phased Array 3.5MHz
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*									
Abdominal									
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		N	N	N	N	N	N	Note 1	Note 5, 6
Small Organ *(See Note 4)*									
Neonatal Cephalic		N	N	N	N	N	N	Note 1	Note 5, 6
Adult Cephalic									
Cardiac		N	N	N	N	N	N	Note 1	Note 5, 6
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E Other Indications or Modes
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (N)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (N)
Note 6: Tissue Harmonic Imaging (N)
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David G. Hoyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: P3-7AC, Phased Array 4.5MHz
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*									
Abdominal									
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		N	N	N	N	N	N	Note 1	Note 5, 6
Small Organ *(See Note 4)*									
Neonatal Cephalic		N	N	N	N	N	N	Note 1	Note 5, 6
Adult Cephalic		N	N	N	N	N	N	Note 1	Note 5, 6
Cardiac									
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E
Other Indications or Modes
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler (N)
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (N)
Note 6: Tissue Harmonic Imaging (N)
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David A. Hagan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: 2.0CW, Static CW 2.0MHz
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*									
Abdominal									
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric					N				
Small Organ *(See Note 4)*									
Neonatal Cephalic									
Adult Cephalic									
Cardiac					N				
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K990970, SA 6000C/ UM 400C system; E = added under Appendix E
Other Indications or Modes
Note 1: PWD/Color Doppler, PWD/Power Doppler, CWD/Color Doppler, CWD/Power Doppler
Note 2: Includes imaging for guidance of biopsy
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging
Note 6: Tissue Harmonic Imaging
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David A. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: S-VAW3-5, Volume Curved Array 3.5MHz
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*		E	E	E		E	E	Note 1	Note 2, 5, 6
Abdominal		E	E	E		E	E	Note 1	Note 2, 5, 6
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		E	E	E		E	E	Note 1	Note 2, 5, 6
Small Organ *(See Note 4)*									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K940942, Voluson C530D system; P^1 = previously cleared in K974813, Voluson C530D Power Doppler mode; P^2 = previously cleared in K993517, Voluson C530D Power Doppler mode; E = added under Appendix E

Other Indications or Modes

Note 1: PWD/Color Doppler, PWD/Power Doppler (E)
Note 2: Includes imaging for guidance of biopsy (E)
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (E)
Note 6: Tissue Harmonic Imaging (P^2)
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

David A. Seppa

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: S-VAW4-7, Volume Curved Array 4.5MHz
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*		P	P	P		P	P	Note 1	Note 2, 5, 6
Abdominal		P	P	P		P	P	Note 1	Note 2, 5, 6
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric		P	P	P		P	N	Note 1	Note 2, 5, 6
Small Organ *(See Note 4)*									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Trans-Rectal									
Trans-Vaginal									
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K992155, C530D Voluson system; P^1 = previously cleared in K974813, Voluson C530D Power Doppler mode; P^2 = previously cleared in K993517, Voluson C530D Power Doppler mode; E = added under Appendix E

Other Indications or Modes

Note 1: PWD/Color Doppler, PWD/Power Doppler (P)
Note 2: Includes imaging for guidance of biopsy (P)
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (P)
Note 6: Tissue Harmonic Imaging (P^2)
Note 7: Abdominal organs and peripheral vessel

Concurrence of ~~CDRH, Office~~ of Device Evaluation (ODE)
(Prescription Use (Per 21 CFR 801.109)

David A. Hyman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002185

Ultrasound Device Indications Statement

510(k) Number:
Device Name: SonoAce 9900 Ultrasound System
Transducer: S-VDW5-8B, Volume Curved Array 6.5MHz
Indications for Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation (*includes simultaneous B-mode)*

Clinical Application	A	B	M*	PWD*	CWD	Color Doppler*	Power (Amp) Doppler*	Combined (Specify)*	Other (Specify)
Ophthalmic									
Fetal *(See Note 3)*									
Abdominal									
Intra-Operative *(See Note 7)*									
Intra-Operative Neurological									
Pediatric									
Small Organ *(See Note 4)*									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transesophageal									
Trans-Rectal		E	E	E		E	E	Note 1	Note 2, 5
Trans-Vaginal		E	E	E		E	E	Note 1	Note 2, 5
Trans-Urethral									
Intra-Vascular									
Peripheral -Vascular									
Laparoscopic									
Muscular-Skeletal Conventional									
Muscular-Skeletal Superficial									
Others(Specify)									

N = new indication; P = previously cleared in K940942, Voluson C530D system; P[1] = previously cleared in K974813, Voluson C530D Power Doppler mode; E = added under Appendix E

Other Indications or Modes

Note 1: PWD/Color Doppler, PWD/Power Doppler (E)
Note 2: Includes imaging for guidance of biopsy (E)
Note 3: Includes infertility monitoring of follicle development
Note 4: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 5: 3D Imaging (E)
Note 6: Tissue Harmonic Imaging
Note 7: Abdominal organs and peripheral vessel

Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
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